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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/414,384	10/07/1999	ANDREW CLARK	0037.00	3236

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NEKTAR THERAPEUTICS
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EXAMINER	
LEWIS, AARON J	

ART UNIT	PAPER NUMBER
3743	

DATE MAILED: 09/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/414,384	CLARK ET AL.	
	Examiner	Art Unit	
	AARON J. LEWIS	3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 June 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

1. Each of the information disclosure statements filed 04/17/2001 and 09/28/2001 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 21-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Howe et al. ('520).

As to claim 21, Howe et al. disclose a device (fig.1a) for controlling the delivery of an aerosolized active agent to the lungs of a human patient, said device comprising a valve (152,153) that provides a high flow resistance of at least 0.4 (cm H2O)1/2/SLM at the onset of the patient's inhalation and that subsequently opens to provide a lower flow resistance (col.3, lines 4-8 and lines 25-33), wherein the lower flow resistance allows for a higher flow rate through the device.

The valve (152,153) of Howe et al. provide a high flow resistance at the onset of a patient's inhalation by closing at least partially (fig.3b) against an inhalation flow rate that exceeds the intended flow rate and subsequently opens (fig.3a) thereby providing a lower flow resistance against an inhalation flow rate that falls below the maximum intended flow rate (col.7, lines 56-64). Inasmuch as the valve of Howe et al. is expressly disclosed as being designed and fabricated to provide specific amounts of resistance to a range of inhalation flow rates and/or inhalation pressures (col.5, lines 11-22; col.7, lines 56-64), it would have been obvious to modify the valve of Howe et al. to exert a flow resistance of any desired amount including at least 0.4 (cm H2O)1/2/SLM as an obvious matter of design choice because the valve of Howe et al. is expressly disclosed as being fabricated and designed differently for different patient's needs.

As to claims 22 and 23, Howe et al. as discussed above with respect to claim 21 disclose specific customizing of the valve (152,153) to achieve a specific ambient air input to mix with nebulized aerosol (col.5, lines 11-22). It would have been obvious to modify the valve of Howe et al. to exert a high flow resistance of any desired amount including between 0.4 and 2 (cm H2O)1/2/SLM and a low flow resistance of any desired amount including between 0 and 0.3 (cm H2O)1/2/SLM as an obvious matter of design choice because the valve of Howe et al. is expressly disclosed as being fabricated and designed differently for different patient's needs. Howe et al. (fig.3b) is illustrative of a high flow resistance and (fig.3a) is illustrative of a low flow resistance.

As to claims 24 and 25, Howe et al. (col.7, lines 59-60) disclose a flow rate of 0.5 liters per second as an optimum flow rate for adult patients. This translates into 30 liters

per minute which is within the claimed range of 15-80 liters per minute during low flow resistance. As a patient inhalation depth increases above this optimum value valve (152,153) exerts more resistance against the patient's inhalation as exemplified by a high flow resistance (fig.3b) thereby limiting the flow rate in proportion to the depth of inhalation to a flow rate including 15 liters per minute.

As to claims 26 and 27, the duration of high flow resistance and/or low flow resistance exerted by the valve (152,153) of Howe et al. varies in dependence upon the duration of a patient inhalation flow rate which exceeds the optimum flow. Therefore, the valve of Howe et al. will exert a flow resistance for a variable duration of time including 5 seconds or 10 seconds in dependence upon how long a patient is inhaling outside the target rate.

Claims 28-36 are substantially equivalent in scope to claims 21-27 and are included in Howe et al. for the reasons set forth above with respect to claims 21-27.

Response to Arguments

1. Applicant's arguments filed 10/17/2005 have been fully considered but they are not persuasive. Applicant's arguments are based upon the contention that Howe et al. disclose a device that operates oppositely to that of the claimed invention by providing low flow resistance at the onset of inhalation and subsequently provides high flow resistance. While this scenario may be accurate when a patient starts out with a weak inhalation and finishes with a strong inhalation, this is not the case for all inhalations. In figs.3a-c Howe et al. illustrate how the valve responds to a weak inhalation (valve fully open fig.3a), a medium inhalation (valve partially closed fig.3b) and a strong

inhalation (valve fully closed fig.3c). The thrust of Howe et al. device is to encourage a patient to inhale at an appropriate strength in order to achieve optimum distribution of aerosolized medicament (col.7, lines 55-64). To that end and given the manner of operation of the inhalation valve as illustrated in figs.3a-c, if a patient starts inhalation by inhaling strongly (enough to close the inhalation valve as illustrated in fig.3c), it is reasonable to expect that patient to reduce their inhalation strength because they will not receive medicament. Upon reducing the strength of their inhalation (enough to permit the inhalation valve to at least partially open as illustrated in fig.3b), it is clear that the valve would open (at least partially) and provide a lower flow resistance thereby allowing a higher flow rate (col.5, lines 3-5) through the device as illustrated in fig.3b of Howe et al..

2. Applicant's arguments filed 06/13/2006 have been fully considered but they are not persuasive. Applicant's argument that a strong inhalation could not be coincident with the onset of patient inhalation is not supported by any factual evidence from the disclosure of Howe et al. nor any factual evidence provided by applicant; accordingly, applicant's argument is not persuasive. Howe et al. (col.3, line 4+; col.3, line 25+) expressly disclose strong patient inhalation and heavy patient inhalation. There is no disclosed evidence to indicate that the "strong" and "heavy" patient inhalations are not occurring throughout a given inhalation including at the onset.

Applicant's argument that Howe et al. teach away from applicant's claimed invention by teaching against any alteration in flow is not persuasive because while Howe et al. may disclose regulation of flow resistance in order to provide for a constant flow rate, it

expressly discloses permits a higher flow rate through valve (152,153) when the flow rate through the valve is within a desired range. While Howe et al. may perform this function for a reason other than applicant's reason does not prevent it from being properly applied as prior art.

Conclusion

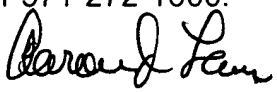
3. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AARON J. LEWIS whose telephone number is (571) 272-4795. The examiner can normally be reached on 9:30AM-6:00PM M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, HENRY A. BENNETT can be reached on (571) 272-4791. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



AARON J. LEWIS
Primary Examiner
Art Unit 3743

Aaron J. Lewis
September 01, 2006